

**REMARKS**

Reconsideration and withdrawal of the rejections of the October 25, 2006 Office Action is respectfully requested in view of the amendments and remarks herein. The Examiner is thanked for withdrawing the written description rejection and the art rejections.

**I. STATUS OF THE CLAIMS AND FORMAL MATTERS**

Claims 1-3, 5-7, 9-32 and 65 are now pending. Claim 65 has been amended, without prejudice, without admission, without surrender of subject matter, and without any intention of creating any estoppel as to equivalents.

No new matter is added.

It is submitted that these claims are and were in full compliance with the requirements of 35 U.S.C. §112. In addition, the amendment and remarks herein are not made for the purpose of patentability within the meaning of 35 U.S.C. §§101, 102, 103 or 112; but rather the amendments and remarks herein are made simply to round out the scope of protection to which Applicant is entitled.

**II. THE OBJECTION TO THE SPECIFICATION IS OVERCOME**

The Office Action stated that the specification was objected to as having two separate descriptions of the figures, each of which provided a description of figures 1-12. Applicants have amended the specification herein, and will be providing new drawings in order to remove the duplicate numbering under separate cover. Accordingly, reconsideration and withdrawal of the objection to the specification is respectfully requested.

**III. THE REJECTIONS UNDER 35 U.S.C. §112 ARE OVERCOME**

Claim 65 was rejected under 35 U.S.C. §112, first paragraph, because the specification is allegedly not enabled for the "inhibiting" of breast cancer. The rejection is respectfully traversed.

Although Applicants maintain that the specification does provide enablement for the inhibition of breast cancer, in order to advance prosecution, claim 65 has been amended herein to remove the "inhibiting" recitation, such that the rejection is now moot. Accordingly,

reconsideration and withdrawal of the rejection under 35 U.S.C. §112, first paragraph is respectfully requested.

#### IV. THE DOUBLE PATENTING REJECTIONS ARE OVERCOME

Claims 1-3, 5-7, 9-32 and 65 were rejected on the ground of nonstatutory obviousness-type double patenting as allegedly being unpatentable over claims of U.S. Patent Nos. 5,830,886, 6,903,084 and US Application Nos. 10/367,114 and 10/955,962, as well of patents and applications listed in paragraph 15 of the previous Office Action.

The Office Action states that while the pending claims are not identical to those of the cited patents and applications, the present claims are obvious as the cited patents and applications allegedly encompass the inhibition of steroid sulphatase utilizing similar substituted 3-sterol sulphamates and/or steroid sulphamates having substitution on the A-ring.

Applicants again reiterate that a finding of obviousness-type double patenting turns on whether the invention defined in a claim in the application in issue is an obvious variation of the invention defined in a claim of a prior patent. *See, e.g., In re Berg*, 46 U.S.P.Q.2d, 1226 (Fed. Cir. 1998). In order for an obviousness-type double patenting rejection to stand, the Examiner must show that the claims in this application are obvious **based solely on the claims in the prior patent**; the disclosure in the prior patent cannot be used as prior art.

The Office Action agreed with this statement, but alleged that "those portions of the specification, which provide support for the patent claims, can be examined and considered when addressing the issue of whether a claim in the application defines an obvious variation of an invention in the cited reference." Office Action at 6.

Applicants again assert that even with reading the claims of the cited documents in view of the specifications, the double patenting rejection should be withdrawn. Nowhere is there a teaching of a compound having a steroidal ring structure having a sulphamate substituent on the A-ring and at least one other substituent at one or more of the 2- and 4-positions, wherein the 2- and 4-positions cannot both be H. The Office Action alleges that some of the claims of the cited references recited 2-substituted steroid nucleuses, however, Applicants respectfully submit that maintenance of the double patenting rejections on the sole basis of such a statement fails to take into consideration the remainder of the recitations in the present claims, namely that the 2- and 4-positions cannot both be H.

Indeed, the instant invention is directed to *inter alia*, compounds having a steroidal ring structure with a sulphamate substituent on the A-ring, wherein the compounds have at least one other substituent at one or more of the 2- and 4-positions, wherein the 2- and 4-positions cannot both be H. The instant application has identified that these compounds provide advantages over the steroidal sulphamate compounds known in the art. More specifically, as described previously, it has been demonstrated that the claimed A-ring modified compounds are potent inhibitors of steroid sulphatase that do not stimulate uterine growth, in contrast to compounds such as oestrone-3-*O*-sulphamate (EMATE), to which at least a portion of the cited references are drawn..

The surprisingly results which place the claims of the present application in an advantageous position over those of the cited patents or co-pending applications cited by the Examiner teach indicate that the present claims cannot be obvious from the cited references. One of skill in the art would have no reason to believe that preparing a substituted compound as claimed herein would have these improved properties.

Applicants would appreciate the opportunity to discuss this rejection, and the improvements found in the presently claimed compounds, with the Examiner and her supervisor, and have therefore requested an interview herein.

Accordingly, reconsideration and withdrawal of the double patenting rejections are respectfully requested.

#### **REQUEST FOR INTERVIEW**

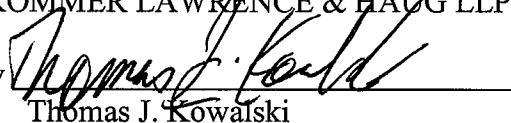
If any issue remains as an impediment to allowance, prior to issuance of any paper other than a Notice of Allowance, a further interview, is respectfully requested, with the Examiner and her supervisor, and, the Examiner is respectfully requested to contact the undersigned to arrange a mutually convenient time and manner for such an interview.

**CONCLUSION**

In view of the remarks made herewith, the application is in condition for allowance. Favorable reconsideration of the application, and prompt issuance of a Notice of Allowance are earnestly solicited. The undersigned looks forward to hearing favorably from the Examiner at an early date.

Respectfully submitted,  
FROMMER LAWRENCE & HAUG LLP

By



Thomas J. Kowalski  
Reg. No. 32,147  
Angela M. Collison  
Reg. No. 51,107  
(212) 588-0800